510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
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Contact: Liu Yi
Date of Application: 06/20/2011

2.0 Device information

Trade name: Fully Automatic Electronic Blood Pressure Monitor
Common name: Noninvasive blood pressure measurement system
Classification name: Noninvasive blood pressure measurement system

3.0 Classification

Production code: DXN- Noninvasive blood pressure measurement system.
Regulation number: 870.1130
Classification: II
Panel: Cardiovascular

4.0 Predicate device information

1	Manufacturer: Andon Health Co., Ltd. Device: KD-557 Fully Automatic Electronic Blood Pressure Monitor 510(k) number: K100014
2	Manufacturer: Andon Health Co., Ltd. Device: KD-5963NU Fully Automatic Electronic Blood Pressure Monitor 510(k) number: K101010

5.0 Device description

KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J Fully Automatic Electronic Blood Pressure Monitor are for use by medical professionals or at home and are non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

They are designed and manufactured according to ANSI/AAMI SP10--manual, electronic or automated sphygmanometers.

The operational principle is based on oscillometric and silicon integrates pressure sensor technology. It can calculate the systolic and diastolic blood pressure, and display the result on the LCD. If any irregular heartbeat is detected, it can also be shown on the LCD. More over, it also calculates the average of the last three measurements.

6.0 Intended use

KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J Fully Automatic Electronic Blood Pressure Monitor are for use by medical professionals or at home and are non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

The intended use and the indication for use of KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J, as described in the labeling are the same as their predicate devices KD-557 and KD-5963NU.

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7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar
Biocompatibility	Identical
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

8.0 Discussion of non-clinical and clinical test performed

Non-clinical Tests have been done as follows:

a. Electromagnetic compatibility evaluation according to IEC 60601-1-2;
b. Electrical safety test according test to IEC 60601-1 ;
c. Safety and performance characteristics of the test according to SP10

None of the test demonstrates that KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J bring new questions of safety and effectiveness.

Clinical Test Concerning the Compliance of ANSI/AAMI SP10

From the technical point of view, the subject device KD-557J, KD-5963NGJ, KD-5963NUJ and KD-5971J are identical to its predicate device KD-557 and KD-5963NU. The difference between the subject devices and their predicate devices do not affect the clinical accuracy in terms of blood pressure detection. The clinical test report of KD-598(K083395) is applicable to our subject devices. KD-5031NJ use the same cuff, the same design principle and the same algorithm with KD-5961(K093387), so the clinical test report of KD-5961 is applicable to KD-5031NJ.

9.0 Performance summary

KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J Fully Automatic Electronic Blood Pressure Monitor conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- EN 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007.
- AAMI SP10:2002, Manual, electronic or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A1:2003 –, Amendment 1 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A2:2006 –, Amendment 2 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

10.0 Comparison to the predicate device and the conclusion

Our device KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J Fully Automatic Electronic Blood Pressure Monitor is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-557(K100014) and KD-5963NU(K101010).

KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J are very similar with their predicate devices in the intended use, the design principle, the material, the performance and the applicable standards. The main difference is that the hypertension classification of KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J are changed. KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J will use the JNC hypertension classification while their predicate device KD-557 and KD-5963NU use the WHO hypertension classification.

However, the test and evaluation in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness to the new devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 9 2011

Andon Health Co., Ltd.
c/o Ms. Elizabeth M. Bierman
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

Re: K111826
Trade/Device Name: Fully Automatic Electronic Blood Pressure Monitor with models: KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: November 10, 2011
Received: November 10, 2011

Dear Ms. Bierman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : K111826

Device name: KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J Fully Automatic Electronic Blood Pressure Monitor

Indications for use:

KD-557J, KD-5031NJ, KD-5963NGJ, KD-5963NUJ and KD-5971J Fully Automatic Electronic Blood Pressure Monitor are for use by medical professionals or at home and are non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

Prescription use _____ AND/OR Over-The-Counter Use YES
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111826